Table . Corn Oil: Effect on Blood Lipids, Design Type 3 Studies

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
Cuchel et al., 1996	Non- ran- dom- ized trial, CO	C	+	Purpose: To determine whether consumption of stick oil margarine impacts endogenous chol synthesis rates and susceptibility of LDL to oxidation in humans  Sample: 14 middle-aged and elderly hypercholesterolemic subj (8 females, 6 males)  Inclusions: LDL>3.36 mmol/L  Exclusions: Smoking; chronic illness; use of meds affecting lipids	Run-in Period: Baseline diet: 15% PRO, 49% CHO, 36% fat (15% SFA, 15% MUFA, 6% PUFA), ~128 mg chol  32 d  TX/Duration Two 32-d diet phases; 1/5 or 2/3 total fat energy provided as corn oil or corn oil margarine in stick form  Dose/Form: 1) TX 1: Corn oil-enriched diet (7% SFA, 9% MUFA, 11% PUFA) 2) TX 2: Stick corn oil margarine-enriched diet (8% SFA, 12% MUFA, 8% PUFA)  Dietary Intake During Study: Total fat: 30% TE PUFA (% TE): Corn oil: 11.21±0.52 Corn oil margarine: 8.30±0.16 SFA: ≤8% TE Chol: <85 mg/4.2 MJ	Outcome Measures: Serum lipids Chol synthesis rates Susceptibility of LDL oxidation  Results: % change in lipid values following corn margarine diet compared with corn oil diet:     TC: 5.5±11 (P=0.039)     LDL: 9±16 (P=0.058)     TC/HDL: 9±14 (P=0.37)  NS diff in HDL or TG bet diets  Proportion of rapidly cycling pool of chol synthesized/d higher after corn oil diet vs corn margarine diet (P=0.80)  Susceptibility of LDL to oxidation NS diff bet diets	Author's Conclusions: "In summary, our data suggest that replacing corn oil with corn oil margarine in the stick form impaired the clearance of endogenously synthesized cholesterol. Additionally, within the content of the low-fat diet, the one-to-one substitution of hydrogenated fat for unhydrogenated oil did not significantly impact the susceptibility of LDL to oxidation"  Reviewer's Comments: Regimen or diet protocol poorly explained; does not explain if all subj consumed TX diets in same order

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					Isocaloric		
					Food supplied by researchers		
					Dietary Intake Assessment/Frequency: None		
					Study Visits/ Measurements: 4 fasting blood samples collected during final wk of each dietary phase		
					Washout Period: Subj ate normal diets, duration not indicated		
Imaki et al., 1989	Non- ran- dom- ized trial	С	+	Purpose: To study effect of lard and corn oil on serum lipids	Run-in Period: 7 d Subj ate usual diets to establish basal diet	Outcome Measures: Lipids TC fraction: HDL, VLDL+LDL Lipoprotein fraction: HDL, LDL	Author's Conclusions: "It is concluded that lard and corn oil have different and specific
				Sample: 4 Japanese men	TX/Duration: 1) CNTL diet: 10 g/d fat (4 g/d SFA, 6 g/d PUFA),	Results: % change not reported	roles in lipid metabolism"
				Inclusions: Healthy young men age 21-24 y  Exclusions: Alcohol consumption	40 mg/d chol x 7 d 2) Lard diet: basal diet plus 30 g/d lard x 7 d 3) Corn oil diet: basal diet plus 30 g/d corn oil x 7 d	Change in TC compared to CNTL: Corn oil diet: decr from 141±26 mg/dl to 111±22 mg/dl ( <i>P</i> <0.05)	Reviewer's Comments: Very small sample; subj continued normal daily living with exception of heavy
				and smoking	ŭ	Change in HDL compared to	exercise; tea and

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					Diets consecutive; no washout bet  Dose/Form:  1) CNTL diet: based on usual intake 2) Lard diet: 30 g/d lard 3) Corn oil diet: 30 g/d corn oil  Dietary Intake During Study: Total fat (% TE) Corn oil: 14 Lard: 14 CNTL: 3 PUFA (% TE) Corn oil: 13 Lard: 2 CNTL: 2 SFA (% TE) Corn oil: 1 Lard: 12 CNTL: 1 Chol (mg/d): 40 for each group Calories: approx 2600/d  Dietary Intake Assessment/Frequency:	CNTL: Corn oil diet: incr from 31.2±3.8 mg/dl to 41.9±4.6 mg/dl (P<0.05)  Change in TG compared to CNTL: Corn oil diet: incr from 164±31 mg/dl to 169±40 mg/dl (P<0.01)  Phospholipids unchanged by experimental diets  Change in HDL fraction of TC compared to CNTL: Corn oil diet: incr from 28.7±2.3% to 36.8±2.8% (P<0.05)  Change in VLDL+LDL fraction of TC compared to CNTL: Corn oil diet: decr from 71.3±2.3% to 63.2±2.8% (P<0.01)  HDL fraction of lipoprotein incr sig (P<0.05) from lard to corn oil diet (33.7±5.7 to 41.5%);  LDL fraction of lipoprotein incr sig	water given ad lib; short experimental time period; fat in basal diet low/CHO high; subj had normal lipid values prior to study entrance
					Subj lived in metabolic ward and ate experimental diets; amt of	( <i>P</i> <0.05) to 44.3 <u>+</u> 3.1% on lard diet, then decr to 36.3+2.5% on corn oil diet (NS)	
					all foods eaten recorded;	serior dist (110)	

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					time of meals same each d; blood tests done every 4-5 d		
Mitchell et al., 1989	Non- ran- dom- ized trial, CO	С	NA	Purpose: To compare digestibility of cocoa butter and corn oil as well as influence of dietary fats on fecal FA excretion pattern in human subj  Sample: 6 healthy males  Inclusions: Healthy  Exclusions: HX of either metabolic or endocrine disease; gastrointestinal disturbances	Run-in Period: Low fat diet (30-40 g fat/d) for 3 d before each 3-d test fat diet regimen  TX/Duration: 2 test fat diets with CO: 1) TX 1: Corn oil 2) TX 2: Cocoa butter  3 d each diet  Dose/Form: Specially formulated cookies providing 40% of total energy intake or 97-98% of total dietary fat from following fats: 1) Corn oil 2) Cocoa butter  Dietary Intake During Study: Fat (ave g/3 d): Corn oil: 390 Cocoa butter: 383  Dietary Intake Assessment/Frequency: FFQ and 24-h food	Outcome Measures: Fat absorption  Results: Percentage fat excreted sig higher (P≤0.001) when subj consumed cocoa butter (10.8±3.2%) vs corn oil (3.5±1.0%) diet	Author's Conclusions: "These results indicate that the digestibility of cocoa butter is significantly less than corn oil and may explain, in part, previous reports of a neutral effect of dietary cocoa butter on plasma cholesterol concentrations"  Reviewer's Comments: Small sample size; outcome measures limited in scope

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					record before study initiation		
					Dietary records kept for all foods consumed		
					Study Visits/ Measurements: Fecal samples collected during and 1-2 d after each study period		
					Washout Period: 7 d – usual diet		
Zanni et al., 1987	Non- ran- dom- ized trial	С	+	Purpose: To evaluate effect of commonly used dietary fats alone or in combination with egg yolk chol on plasma lipids, lipoproteins and apoproteins of human subj consuming controlled natural diets  Sample: 9 healthy women	Run-in Period: None  TX/Duration: 4 diet protocols made up of regular foods; diets varied only in type of fat and amt of chol used in muffins: 1) TX 1: Corn oil 2) TX 2: Corn + chol 3) TX 3: Lard 4) TX 4: Lard + chol	Outcome Measures: Lipids Lipoproteins Apoproteins  Results: When compared to ad lib diets, corn diet sig reduced (P < 0.05) TC, HDL, LDL, total apoprotein A-I, total apoprotein B, LDL-apoprotein B levels and ratios of LDL-chol/LDL-apoprotein B and HDL/apoprotein A-I	Author's Conclusions: "The current study confirms many others demonstrating that plasma cholesterol levels can be decreased by reducing the cholesterol content and increasing the polyunsaturated fat content of the diet"
				Inclusions: Healthy; menstruating	CO; 15 d each  Dose/Form: 4-8 muffins with diff fats: 1) Corn oil	When compared to ad lib diets, corn + chol diet sig reduced ( <i>P</i> < 0.05) TC, LDL and ratios of LDL-chol/LDL-apoprotein B and LDL chol/HDL and sig incr ( <i>P</i> < 0.05)	Reviewer's Comments: None

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				Exclusions: Use of drugs or alcohol; smoker	2) Corn+: Corn oil + additional chol (egg yolk) 3) Lard 4) Lard+: Lard + additional chol (egg yolk)  Dietary Intake During Study: Total fat: 31% TE PUFA: 31% TE in corn oil and corn oil+ groups P/S ratio: Corn oil: 2.14 Corn+: 2.14 Lard: 0.64 Lard+: 0.64 Chol (mg/d): Corn oil: 130 Corn+: 875 Lard: 130 Lard+: 875 Ad lib: 169±30 Calories: 1500-1800 kcal/d (ave 1767±430 kcal/d)  Dietary Intake Assessment/Frequency: 3-d diet records while on ad lib diets	ratios of HDL/apoprotein A-I and apoprotein B/apoprotein A-I  When compared to ad lib diet, lard diet sig decr ( <i>P</i> < 0.05) TC, LDL, total apoprotein A-I, total apoprotein B and LDL-apoprotein B levels and sig incr ( <i>P</i> < 0.05) total TG levels; ratios of LDL-chol/LDL-apoprotein B and LDL chol/HDL sig decr while HDL/apoprotein A-I and HDL/TC sig incr  When compared to ad lib diet, lard + chol diet NS changes  When compared to corn oil diet, corn + chol diet sig incr ( <i>P</i> <0.05) TC, HDL, LDL, total apoprotein B and LDL-apoprotein B levels; ratios of LDL-chol/LDL-apoprotein B, HDL/TC, HDL/apoprotein A-I and apoprotein B/apoprotein A-I sig incr  When compared to corn oil diet, lard diet sig incr ( <i>P</i> <0.05) TC, HDL, apoprotein B and HDL/apoprotein A-I  When compared to corn oil diet, lard + chol diet sig incr ( <i>P</i> <0.05) TC, HDL, LDL, total apoprotein A-I  TC, HDL, LDL, total apoprotein A-I	

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			Study Visits/ Measurements: Fasting plasma samples collected first 2 d preceding diet period, d 10 and last 2 d of each 15-d diet period  Washout Period: 3-wk ad lib diet bet each TX diet	I, total apoprotein B and LDL-apoprotein B levels and ratios of LDL-chol/LDL-apoprotein B and HDL/apoprotein A-I  Effects of dietary lipids on lipoprotein composition (% change): LDL-chol Corn to corn+: 29±32 (P<0.05) Lard to lard+: 23±14 (P<0.05) Corn to lard: 20±22 (NS) Corn to lard: 46±36 (P<0.05) LDL-apoprotein B Corn to corn+: 17±18 (P<0.05) Lard to lard+: 9±12 (NS) Corn to lard: 9±19 (NS) Corn to lard: 18±18 (P<0.05) LDL-chol/LDL-apoprotein B Corn to corn+: 9±14 (NS) Lard to lard+: 13±10 (P<0.05) Corn to lard: 24±25 (P<0.05) HDL Corn to corn+: 28±16 (P<0.05) Lard to lard+: 2±16 (NS) Corn to lard: 22±21 (P<0.05) Corn to lard: 22±21 (P<0.05) Apoprotein A-I Corn to corn+: 8±13 (NS) Lard to lard+: 4±10 (NS) Corn to lard: 7±9 (NS) Corn to lard: 7±9 (NS) Corn to lard+: 11±11 (P<0.05) HDL/Apoprotein A-1	

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						Corn to corn+: 20±7 (P<0.05) Lard to lard+: -2±16 (NS) Corn to lard: 14±17 (P<0.05) Corn to lard+: 10±11 (P<0.05)  NS variation in VLDL, TG or apoprotein E levels with these diets	
Snook et al., 1985	Non- ran- dom- ized trial	С	+	Purpose: To study effect of moderate to very low fat and CHO diets on serum lipids  Sample: 12 subj (6 male, 6 female)  Inclusions: Healthy male and female college students;19-33 y of age; within 10% of desirable wt  Exclusions: Subj on meds other than mild analgesics	Run-in Period: None  TX/Duration: EXPERIMENT 1 (in order of TX): 1) Conventional food diet (42% fat, 44% CHO, 305 mg/d chol) x 7 d 2) Moderate fat diet 1 (corn oil; 32% fat, 53% CHO, 0 mg/d chol) x 7 d 3) Moderate fat diet 2 (32% fat, 55% CHO, 0 mg/d chol) x 7 d 4) Low fat diet 1 (9% fat, 74% CHO, 0 mg/d chol) x 7 d 1 adjustment d before each period included test meals with 22 to 40 g corn oil, depending on caloric intake of subj; blood taken	Outcome Measures: Lipids Free chol Esterified chol  Results: EXPERIMENT 1:  Baseline measures of lipids not reported; no total or % change reported  TC sig lower when subj fed moderate and low fat diet vs conventional diet ( <i>P</i> <0.0001 for both). Moderate fat diet 1 (corn oil) more sig decr TC (158±8 mg/dl) than moderate fat diet 2 (corn+soy oil) (183±7 mg/dl) and low fat diet 1 (safflower oil, MCT) (185±12 mg/dl) ( <i>P</i> <0.0001)  Experimental period had sig effect on TC ( <i>P</i> =0.0025); subj on moderate fat diet 1 (corn oil)	Author's Conclusions: "In summary, the data reported herein show that a cholesterol-free moderate fat diet with polyunsaturated fat produced favorable changes in serum lipoprotein parameters associated with CHD. Low and very low fat diets tended to reduce serum HDL-cholesterol levels more than total cholesterol levels"  Reviewer's Comments: Kcals adjusted to maintain body wt; subj allowed only caffeinefree, sugar-free beverages and gum

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				1 and 2 h after meal  EXPERIMENT 2 (in order of TX):  1) Conventional food diet (listed above) x 7 d  2) Low fat diet 1 (listed above) x 7 d  3) Very low fat diet 1 (3% fat, 83% CHO, 0 mg/d chol) x 7 d  4) Very low fat diet 2 (1% fat, 82% CHO, 0 mg/d chol) x 7 d  5) Conventional food diet (listed above) x 5 d  No adjustment d  EXPERIMENT 3 (in order of TX):  1) Conventional food diet (listed above) x 7 d  2) Low fat diet 1 (listed above) x 7 d  3) Low fat diet 2 (9% fat, 74% CHO, 0 mg/d chol) x 7 d  4) Low fat diet 3 (9% fat, 74% CHO, 0 mg/d chol) x 7 d  On d 7 of each period all subj consumed 6 g fat; on	during 1st period had sig decr TC vs subj on same diet during final wk of period  HDL sig decr when subj on low and moderate fat diets vs conventional diet; low fat diet 1 (safflower oil, MCT) resulted in greatest decr in HDL (25%); HDL experimental period effect NS  TG incr sig ( <i>P</i> <0.05) with low fat diet 1 (safflower oil, MCT) (approx 120 mg/dl) vs conventional diet (approx 90 mg/dl); period effect NS  EXPERIMENT 2:  Lipid levels not reported  Low and very low fat diets resulted in sig changes in all serum lipids except free chol ( <i>P</i> <0.0001 for all); TC and HDL decr; TG incr  EXPERIMENT 3:  Lipid levels not reported  TC and esterified chol sig decr ( <i>P</i> =0.0000) on low fat diets 1 (safflower oil, MCT), 2 (safflower	ad lib; conventional foods and dietary formulas used; diets within experimental periods given in random order; controlled portions used; short dietary periods

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					adjustment d all subj given test meal of moderate fat diet 1 plus extra corn oil to provide total of 50 g corn oil; serum TG measured before and 2 h postmeal  Dose/Form:  1) Conventional food diet: 42% fat, 44% CHO, 305 mg/d chol, P/S ratio: 0.1  2) Moderate fat diet 1: 32% fat as corn oil; 53% CHO as corn solids; 0 mg/d chol; P/S ratio: 4.1  3) Moderate fat diet 2: 32% fat as mediumchain TG, corn and soy oil; 55% CHO as corn solids; 0 mg/d chol; P/S ratio: 0.67  4) Low fat diet 1: 9% fat as safflower oil, mediumchain TG; 74% CHO as glucose, oligo- and polysaccharides, sucrose; 0 mg/d chol; P/S ratio: 0.86  5) Low fat diet 2: 9% fat as safflower oil, mediumchain TG; 74% CHO as glucose, oligo- and polysaccharides, sucrose; 0 mg/d chol; P/S ratio: 0.86  5) Low fat diet 2: 9% fat as safflower oil, mediumchain TG; 74% CHO as glucose, oligo- and	oil, MCT) and 3 (safflower oil, MCT)  HDL sig decr ( <i>P</i> =0.0000) on low fat diets 1 (safflower oil, MCT), 2 (safflower oil, MCT) and 3 (safflower oil, MCT); levels not reported  TG sig incr ( <i>P</i> =0.0000) on low fat diets 1 (safflower oil, MCT), 2 (safflower oil, MCT) and 3 (safflower oil, MCT)	

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					polysaccharides, sucrose; 0 mg/d chol; P/S ratio: 0.86 6) Low fat diet 3: 9% fat as safflower oil, mediumchain TG; 74% CHO as glucose, oligo- and polysaccharides, sucrose; 0 mg/d chol; P/S ratio: 0.86 7) Very low fat diet 1: 3% fat as safflower oil; 83% CHO as maltodextrin, modified cornstarch; 0 mg/d chol; P/S ratio: 5.5 8) Very low fat diet 2: 1% fat as safflower oil; 82% CHO as glucose oligosaccharides; 0 mg/d chol; P/S ratio: 5.5 Diff bet low fat diets 1, 2 and 3 PRO source  Blood drawn on first d of each experiment and morning following completion of each dietary period		
					Dietary Intake During Study: Total fat (% TE): listed above for all groups		

Year si	e- C gn ype	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				PUFA (% TE)  1) Conventional food diet: not listed  2) Moderate fat diet 1: 32% (corn oil)  3) Moderate fat diet 2: 32% (MCT, corn oil, soy oil)  4) Low fat diet 1: 9% (safflower oil, MCT)  5) Low fat diet 2: 9% (safflower oil, MCT)  6) Low fat diet 3: 9% (safflower oil, MCT)  7) Very low fat diet 1: 3% (safflower oil)  8) Very low fat diet 3: 1% (safflower oil)  SFA (% TE): not reported Chol (mg/d): listed above for all groups Calories: not reported  Dietary Intake Assessment/Frequency: Subj given conventional foods and defined formula diets; defined formula diets consumed in random order; portion controlled meals/formulas weighed and given to subj in metabolic unit		

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Fisher et al., 1983 Non-ran-dom-ized trial	C	+	Purpose: To assess effects of fat saturation and chol on plasma lipids, lipoprotein and apolipoprotein E  Sample: 9 healthy males  Inclusions: Healthy, normolipidemic males; 18-37 y old  Exclusions: Obesity; drug and alcohol use; smoking	Run-in Period: 1-mo ad lib diets  TX/Duration: Period 1: 1) Corn oil (31% of calories), plus egg white PRO (15% of calories), and glucose polymer: sucrose, 3:1 (54% of calories) x 9 d 2) Corn oil (31% of calories) plus 1 g/d chol, plus egg white PRO (15% of calories), and glucose polymer: sucrose, 3:1 (54% of calories) x 9 d  1-mo washout with ad lib diet  Period 2: 1) Coconut oil (31% of calories), plus egg white PRO (15% of calories) x 9 d 2) Coconut oil (31% of calories), and glucose polymer: sucrose, 3:1 (54% of calories) x 9 d 2) Coconut oil (31% of calories) plus 1 g/d chol, plus egg white PRO (15% of calories), and glucose polymer:	Outcome Measures: TC, IDL+LDL, VLDL, HDL, TG, VLDL TG, apolipoprotein E, VLDL apolipoprotein E, IDL+LDL apolipoprotein E  Results: % change not reported; results reported only for diets with chol  Coconut oil diet sig incr all lipid parameters compared to corn oil diet (P<0.01)  Change in TC compared to ad lib diet: Corn oil+chol: 150±18 to 115±12 (P<0.001) Coconut oil+chol: 150±18 to 172±28 (P<0.05)  Change in IDL+LDL compared to ad lib diet: Corn oil+chol: 97±21 to 68±15 (P<0.001)  Change in VLDL compared to ad lib diet: Corn oil+chol: NS diff Coconut oil+chol: 14±6 to 23±7 (P<0.02)  Change in HDL compared to ad lib diet:	Author's Conclusions: "In these experiments, diets containing 31% of calories in the form of coconut oil produced statistically significant elevations in total, VLDL, IDL+LDL, and HDL cholesterol; total, VLDL, and IDL+LDL apoE; and total and VLDL triglycerides when compared to the corn oil-containing diets. Dietary cholesterol had no significant effect on any variable assayed"  Reviewer's Comments: Small sample; interindividual variation; no sig changes in subj wt or screening tests; subj allowed intake of various amts of lettuce, celery, decaffeinated black coffee and sugarless chewing gum as only outside food sources;

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					sucrose, 3:1 (54% of calories) x 9 d  Dose/Form: Corn oil diets: P/S RATIO: 4:1, Mazola brand Coconut oil diets: 92% FA  75% daily calories as formula; 25% nonformula calories as low PRO muffins with either corn oil or coconut oil, 16 ounces/d orange juice and 2 apples/d  Blood samples taken last 3 d of each 9-d interval  Dietary Intake During Study: Total fat (% TE): 31% for all diets PUFA (% TE) Period 1: 31% (corn oil) Period 2: 0% (coconut oil) SFA (% TE): not reported Chol (mg/d): 1 g/d on corn oil plus chol and coconut oil plus chol diets; other 2 diets contained no chol Calories: not reported	Corn oil+chol: 40±8 to 34±5 (P<0.01)  Change in TG compared to ad lib diet: Corn oil+chol: NS diff Coconut oil+chol: 52±16 to 92±30 (P<0.001)  Change in VLDL TG compared to ad lib diet: Coconut oil+chol: 29±12 to 59±16 (P<0.001)  Change in apolipoprotein E compared to ad lib diet: Corn oil+chol: NS diff  Change in IDL+LDL apolipoprotein E compared to ad lib diet: Coconut oil+chol: 3.6±1.4 to 7.6±2.7 (P<0.01)  Change in VLDL apolipoprotein E compared to ad lib diet: Coconut oil+chol: 2.0±0.8 to 6.2±3.5 (P<0.01)  Measure of plasma lipids, lipoprotein or apolipoprotein not specified (i.e., mg/dl)	plasma samples taken several wk before study; all variables measured within normal range in every subj; short TX periods

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					Dietary Intake Assessment/Frequency: Diets prepared and dispensed by research dietitians in clinical research center; subj followed as outpts; caloric requirements estimated from diet HX		
Chance et al., 1969	Non- ran- dom- ized trial	С	-	Purpose: To examine long-term effects on serum lipids of diet rich in PUFA fat in group of newly diagnosed diabetic children  Sample: Diabetic children  CNTL = 16 Corn oil = 18  Inclusions: Not provided  Exclusions: Not provided	Run-in Period: None  TX/Duration: 1) CNTL: Standard regulated CHO diet 2) Corn oil: Diet rich in PUFA made up of corn oil substituted foods  Dose/Form: Corn oil substituted foods  Dietary Intake During Study: Not provided  Dietary Intake Assessment/Frequency: Not provided  Study Visits/ Measurements: Venous blood samples	Outcome Measures: Serum total lipids Serum chol β-lipoprotein  Results: Mean values for all serum lipids consistently lower in corn oil group than CNTL group until 1964, at which time trend reversed (NS, however, owing to wide scatter of results)  Mean substitution of corn oil for dietary fat fell from 80% in 1959- 60 to 18% in 1968  Younger children consuming corn oil had lower mean serum lipid levels than CNTL children of same age; sig for serum chol and β-lipoprotein in 8-10 y age group and serum lipid in 8-9 y age group (P<0.05)	Author's Conclusions: "The results of the first 10 years of a prospective study of the effect of corn-oil and standard diets given to diabetic children since diagnosis suggest that the corn-oil diets currently available in Britain are not acceptable to most diabetic children and adolescents. Attempts to administer such diets may result in hyperpre-betalipoproteinaemia. In most diabetic children, normal serum lipid levels can be maintained with

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					Follow-up Period: Follow-up for 10 y (1958-1968; after 5 y, however, difficulties encountered in obtaining adequate supplies of corn oil substituted foods)	% change and absolute change not provided	adequate diabetic control and a standard diabetic diet"  Reviewer's Comments: None
Kaplan et al., 1965	Non- ran- dom- ized trial	С	Ø	Purpose: To observe effect of corn oil and skim milk vs milk and cream regimen on serum chol in peptic ulcer pts  Sample: 8 ambulatory peptic ulcer pts (6 males, 2 females)  Inclusions: Peptic ulcer pts  Exclusions: None given	Run-in Period: None  TX/Duration: 1) Diet B: GI diet plus 9 h feedings 90 ml milk/cream mixture x 2 wk 2) Diet B <sub>1</sub> : GI diet plus 9 h feedings 90 ml corn oil/skim milk mixture x 2 wk 3) Repeat of diet B for 3 pts x 2 wk No washout reported Blood taken at start of study and postdiet period  Dose/Form: 1) TX 1: Diet B - milk and cream	Outcome Measures: TC  Results: % change not reported  Change in TC (mg/dl) compared to baseline: Diet B <sub>1</sub> (corn oil): 226 to 192 (P<0.05) Diet B: 226 to 245 (no P reported) Diet B repeat: 226 to 276 (no P reported) Change in TC incr sig bet diet B and diet B <sub>1</sub> (corn oil) (P<0.001)	Author's Conclusions: "The substitution of skim milk and corn oil for milk and cream was accompanied by a statistically significant reduction in serum cholesterol far below pre-treatment levels in all patients"  Reviewer's Comments: Small sample size; not randomized; diets labeled as in study; stats not reported for all results; type of milk used not reported for diet B; no washout period reported

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					2) TX 2: Diet B <sub>1</sub> - 85 g corn oil		
					Dietary Intake During Study: Total fat (% TE) Diet B: 53 Diet B1: 48 PUFA (% TE) Diet B: 2 Diet B1: 14 SFA (% TE) Diet B: 31 Diet B1: 11 Chol (mg/d) Diet B: 704 Diet B1: 380 Calories: approx 2345/d  Dietary Intake Assessment/Frequency: Subj admitted to clinical research unit for entire study; meal preparation/distribution methods not reported		
Haust and Beveridge, 1963	Non- ran- dom- ized trial	С		Purpose: To examine changes in fecal elimination of 3 β-hydroxysterols when using formula rations free from chol	Run-in Period: None  TX/Duration: Fat free formula diet for 8 d then switched to corn oil	Outcome Measures: Plasma chol Sterol content of feces  Results: Consumption of fat-free diet in	Author's Conclusions: "These datademonstrate that the overall increase in sterol

Year si	De- C ign Type	uality -,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
			Sample: 2 adult males (1 healthy; 1 diabetic)  Inclusions: Not provided  Exclusions: Not provided	formula diet for another 8 d  Dose/Form:  1) Fat free formula diet: skim milk powder and sucrose  2) Corn oil formula diet: 60% TE corn oil (replacing equicaloric amt of CHO); 0.93% of digitonin-precipitable sterol  Dietary Intake During Study: Not provided  Dietary Intake Assessment/Frequency: None  Study Visits/ Measurements: Feces collected last 4 d of each diet  Fasting plasma chol levels determined on d 0, 4, 8, 12 and 16	case of both subj led to decr in level of plasma chol that dropped further as result of isocaloric substitution of corn oil for CHO  Chol levels in both subj: Fat free diet:  1st subj: From 209 mg/100 mL to 120.1 and 145.4 mg/100 mL on d 4 and 8, respectively 2nd subj: From 165.0 mg/100 mL to 113.0 and 108.5 mg/100 mL on d 4 and 8, respectively  Corn oil diet:  1st subj: From 209 mg/100 mL to 109.6 and 107.3 mg/100 mL on d 4 and 8, respectively 2nd subj: From 165.0 mg/100 mL on d 4 and 8, respectively 2nd subj: From 165.0 mg/100 mL on d 4 and 8  Large incr in amt of fecal unsaponifiable matter excreted by subj on last 4 d of corn oil period due to 3 β-hydroxysterols  Fraction of fecal 3 β-hydroxysterols  Fraction of sitosterol ingested in corn oil  % change not provided	excretion observed when subjects are transferred from a fat-free diet to one high in corn oil is due in large part to an increase in the output of sterols derived from endogenous sources. The association of significant increases in the elimination of endogenous sterol with decreasing plasma cholesterol levels suggests that these 2 phenomena are causally related"  Reviewer's Comments: Small sample size (N=2); short period (8 d); little info provided on dietary protocol

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
Watson, 1963	Non- ran- dom- ized trial	C	Ø	Purpose: To determine if dietary program to reduce chol feasible and whether effects on serum lipids sustained or transient  Sample: 28 male MI pts (43-65 y of age)  Inclusions: Admitted with and survived 1 <sup>st</sup> acute MI attack  Exclusions: DM, renal disease or BP >160/100 after 4 wk in hospital	Run-in Period: None  TX/Duration: 1) TX 1: 1630 kcal low animal fat diet + 57 g corn oil (2045 total kcals; 41.5% of total fat from corn oil) 2) TX 2: 2080 kcal low animal fat diet + 57 g corn oil (2595 total kcals; 40.0% of total fat from corn oil)  >2.5 y  Dose/Form: 57 g corn oil-maize oil — 56% linoleic acid content  Provided to subj in 2 ounce medicine glass; told to take oil as it suited them  Dietary Intake During Study: Total fat (g): TX 1: 80 g TX 2: 85 g Calories: TX 1: 2045 kcals TX 2: 2595 kcals	Outcome Measures: TC  Results: For subj followed for 2 y (N=24): Mean change in TC levels (mg/100 mL) from baseline: 3 mo: -42 mg (P<0.001) 12 mo: -72 mg 2 y: -58 mg (P<0.001)  29.1% mean maximum fall in serum chol  18.2% ave reduction in serum chol from mo 3 to 24  17 pts had >25% maximum fall in serum chol and 17 had >15% maximum fall in serum chol compared to baseline  High degree of correlation bet maximum and mean percentage falls in chol (r=0.94; P<0.001)  For subj followed for 3 ½ y (N=8): Ave chol levels for this group follow closely those of larger group for 1 to 2 y  By end of y 3, mean diff from baseline -41 mg/100 mL (P<0.02)	Author's Conclusions: "This study shows that a diet of about 1,600 to 2,000 calories low in animal fat and supplemented by 57 g of corn oil per day, can produce and maintain a significant reduction in the serum cholesterol level for at least three years"  Reviewer's Comments: None

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
					PUFA, SFA and chol not provided	19.3% mean reduction in serum chol levels from baseline	
					Dietary Intake Assessment/Frequency: Not provided  Study Visits/ Measurements: Baseline chol reading taken on 22 and 29 d after infarction for most pts and 29 d and 8 wk after infarction for those with severe attacks  Ht and wt measured before hospital discharge and anticoagulants discontinued  Pts seen at monthly intervals for 1 <sup>st</sup> 3 mo and thereafter every 3 mo  Substudy: After ≥2 y, investigators discontinued corn oil in 7 subj for 5-mo period; subj continued to follow low animal fat diet; serum chol measured monthly; after 5	After 3 y, mean chol levels not below baseline levels  For substudy subj: Mean chol levels (mg/100 mL): Baseline: 292 12 mo (before corn oil withdrawn): 259 (P<0.01 compared to baseline) 1 mo after corn oil withdrawn: 295 (P<0.05 compared to 12-mo level) 5 mo after corn oil withdrawn: 308 (no P value given) 2 mo after corn oil restarted: 280 (no P value given)  4 subj died during 1st 2 y of trial, assumedly from reinfarction (giving 14.3% mortality rate); 3 other subj died >2 y after study initiation (2 after withdrawing from study)  % change and absolute change not provided	
					mo, corn oil reintroduced		

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
Lloyd et al., 1962	Non- ran- dom- ized trial, con- cur- rent CNTL	C	ØI-	Purpose: To determine whether diet rich in unsaturated fat practicable proposition in long-term management of juvenile diabetics in their own homes, and whether such diet would maintain lower levels of serum β-lipoprotein  Sample: 31 diabetic children (15 CNTL; 16 corn oil)  Inclusions: Recently diagnosed diabetes; pediatric pt  Exclusions: Consumed corn oil diet <6 mo	Run-in Period: None  TX/Duration: 1) CNTL: Dietary fat mainly of animal origin 2) Corn oil: Diet rich in unsaturated fat from corn oil  Diet started within few wk of diabetes diagnosis  All subj received insulin 6 mo  Dose/Form: Not provided  Dietary Intake During Study: Fat intake not limited (Ave total fat: 40% TE corn oil group; 43% TE CNTL group)  CHO intake regulated  Dietary Intake Assessment/Frequency: "Supervised regularly"  Study Visits/	Outcome Measures: Serum lipids Blood sugars  Results: Mean TC levels sig lower in corn oil (176±26 mg/100 mL) than CNTL (199±135 mg/100 mL) group ( <i>P</i> =0.05)  Mean β-lipoprotein levels sig lower in corn oil (264±45 mg/100 mL) than CNTL (333±67 mg/100 mL) group ( <i>P</i> =0.001)  Highly sig diff bet mean values for β-lipoprotein largely due to few high values among CNTLs and some very low values in corn oil group  Mean β-lipoprotein/α-lipoprotein ratio sig lower in corn oil (1.34±0.42 mg/100 mL) than CNTL (1.61±0.44 mg/100 mL) group ( <i>P</i> =0.05)  NS diff in α-lipoprotein, ω-lipoprotein or blood sugar levels bet groups  % change and absolute change not provided	Author's Conclusions: "There can be no doubt that the lower lipids levels in the corn-oil group are mainly due to the high content of unsaturated fat in the diet"  Reviewer's Comments: None

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
Kingsbury et al., 1961	Non- ran- dom- ized trial	С	Ø	Purpose: To assess effects of corn oil and cod liver oil on plasma chol  Sample: 11 healthy males (19-25 y of age)	Measurements: Blood samples collected at 6-mo intervals  Run-in Period: None  TX/Duration: Phase 1 (N=11): subj given diet of 3155 kcals/d with 127 g animal and dairy fat x 3 d; diets	Outcome Measures: TC  Results: P values not reported  Phase 1: TC decr by approx 10 mg/100ml	Author's Conclusions: "In these experiments cod liver oil reduced the plasma cholesterol level at least as much as an equal weight of corn
				Inclusions: Healthy males  Exclusions: None given	changed to 3649 kcals with 169 g/d fat x approx 7 d  Phase 2 (N=8): subj divided into 3 groups and given corn oil or cod liver oil supplements x 10-12 d; group 1 had 2 subj with normal TC, groups 2 and 3 each had 3 subj with incr and decr TC  Dose/Form: Phase 1: no supplements given Phase 2: 1) Group 1: 10 g/d ethyl arachidonate x 11 d, followed by 10 g cod liver oil for undisclosed time	on first regimen; TC incr to original levels within 1 wk  Phase 2: TC in each group decr 20-25%; in smaller doses of 25-30 g/d of cod liver oil and corn oil (N=2), TC decr with FO more sig than with corn oil	Reviewer's Comments: Stat tests and P values not reported; TC incr in subj after supplements discontinued

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
					2) Group 2: 50 g/d corn oil x 12 d, followed by 50 g/d cod liver oil for undisclosed time 3) Group 3: same supplement as group 2 but reverse order  Dietary Intake During Study: Phase 1: Total fat (% TE): 127 g/d (36%), 169 g/d (42%) PUFA (% TE): 12.5% corn oil groups SFA (% TE): not reported Chol (mg/d): not reported Calories: 3155/d, 3649/d Phase 2: Not reported  Dietary Intake Assessment/Frequency: Not reported		
Horlick, 1959	Non- ran- dom- ized trial	С	-	Purpose: To examine whether hypocholesterolemic effect of certain unsaturated fats positive or neutral  Sample:	Run-in Period: Low fat diet  1-2 wk  TX/Duration: 1) TX 1: CNTL period 2) TX 2: Low fat diet	Outcome Measures: Serum-free and TC Lipid phosphorus Lipoprotein chol Fecal fat  Results: Serum chol fell during low fat	Author's Conclusions: "When corn oil was added to a very-low- fat diet, there was no further fall in the serum cholesterol level. There was,

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				6 healthy students Inclusions: Not listed Exclusions: Not listed	period with corn oil added (some subj received incr increments of corn oil from start of low fat diet while others on low fat diet for 1 wk before corn oil started)  1-2 wk  Dose/Form: Fats and oil incorporated into diet  Corn oil 40% TE for most subj; incr increments of 10 g/d up to 70 g/d (40% TE) for 1 subj  Dietary Intake During Study: Total fat (% TE): Low fat (corn oil): 4 CNTL: 45 Chol (mg/d): Low fat (corn oil): 28 CNTL: 512  Diets isocaloric for each individual  Dietary Intake Assessment/Frequency:	phase, but no change in % distribution of lipoprotein-chol fractions  No additional decline in serum chol with addition of corn oil to low fat diet, but assoc with sig incline in β lipoprotein chol  % change and absolute change not provided	however, a decrease in the percent of β lipoprotein cholesterol. This would suggest at 'neutral' role for corn oil"  Reviewer's Comments: None

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
					Diet HX forms  Study Visits/ Measurements: Fasting blood samples collected and wt measured 2x/wk  Fecal samples collected daily		
Rhoads and Barker, 1959	Non- ran- dom- ized trial	С	Ø	Purpose: To test effect of cornoil regimen acceptable to most pts without radical change in usual diet and without use of formula diets on plasma chol levels  Sample: 9 hypercholesterolemic male pts (TC values bet 247 and 331 mg/100 mL; 8 completed)  Inclusions: Hypercholesterolemic; mental diagnosis of schizophrenia; pt in hospital; ambulatory;	Run-in Period: Routine hospital diet Chol samples collected ≥2 wk  TX/Duration: 4 study periods: 1) Low fat diet (70 d) 2) Corn oil (30 cc/meal; 90 cc/d) + low fat diet (92 d) 3) Corn oil (30 cc/meal) + routine hospital diet (62 d) 4) Routine hospital diet (66 d)  Dose/Form: 90 cc corn oil/d – iodine value, 125; linoleic acid, 56.2%; oleic acid, 30.1%; palmitic acid 9.97%;	Outcome Measures: Plasma chol  Results: Mean change in plasma chol: Low fat diet: -44mg/100 mL from baseline after 2 mo Corn oil + low fat diet: -32 mg/100 mL from period 1 Corn oil + hospital diet: +32 mg/100 mL from period 2 (approx -40 mg/100 mL from baseline) Hospital diet: returned to baseline values	Author's Conclusions: "moderate reduction of saturated fats in the diet and addition of corn oil produce significant lowering of values for plasma cholesterol in human subjects with hypercholesterolemia"  Reviewer's Comments: None

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				activity; well nourished but not obese; high plasma chol  Exclusions: Clinical evidence of DM, thyroid dysfunction, HTN or hepatic disease	acid/SFA ratio, 4.3:1  Dietary Intake During Study: Routine hospital diet: Total fat: 103 g animal fat + 22 g veg fat Calories: 2780 kcals (ave)  Reduced fat diet: Total fat: 57 g (±10 g) of which 50 g from animal fat Calories: 2533 kcals (ave)  Dietary Intake Assessment/Frequency: None  Study Visits/ Measurements: Plasma chol determined at mo intervals		
Grande et al., 1958	Non- ran- dom- ized trial	С	Ø	Purpose: To determine whether corn oil contains special chol-lowering substance not accounted for as FA glyceride, presumably in unsaponifiable fraction  Sample:	Run-in Period: 6 wk on standard "house diet"  TX/Duration: Switchback design; low fat diet with 100 g experimental fat added (ave 28% of total calories)	Outcome Measures: Chol  Results: Change in chol values (mg/100 mL) for corn oil minus other oils (observed/predicted): Olive oil: -27.2 ±3.6/-17.3 Cottonseed oil: -19.3±4.2/-11.3 Sunflower seed oil: -9.3±2.8/+2.5	Author's Conclusions: "Comparison of corn oil with 4 other oils of the linoleic-oleic acid type consistently indicated that corn oil in the diet produced slightly lower serum cholesterol values than those predicted,

Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				93 healthy schizophrenic men (39-66 y of age)  Inclusions: Physically healthy  Exclusions: Acute illness; body wt changes of 2 kg in dietary period or 3 kg in entire experiment	EXPERIMENT N:  1) TX 1: Group W – Low fat diet with safflower oil (3 wk)  2) TX 2: Group X – Low fat diet with corn oil (3 wk) then safflower oil (3 wk)  3) TX 3: Group Y – Not described  4) TX 4: Group Z – Not described  EXPERIMENT O:  1) TX 1: Group A – low fat diet + 100 g mixture of cottonseed and safflower oils + 1.7 g/d unsaponifiable corn oil concentrate (wk 1-3)  2) TX 2: Group B – low fat diet + 100 g mixture of cottonseed and safflower oils + 1.7 g/d unsaponifiable corn oil concentrate (wk 3-6)  Diets adjusted as needed to keep body wt constant  Dose/Form:  1) 100 g corn oil (15% SFA, 26% MUFA, 59%	Safflower oil: +2.7±2.2/+9.1  Magnitude of discrepancy with corn oil observed change vs predicted change substantially same in all experiments, 6.4 to 11.8 mg/100 mL  Every man showed considerable fall in serum chol in changing from "house diet" to either imitation corn oil alone or that oil plus unsaponifiable fraction, grand ave change -42.5 mg chol/100 mL  Something in corn oil but absent from other fats results in ave serum chol about 9 mg% lower than expected when 100 g corn oil ingested daily  Feeding unsaponifiable corn oil fraction assoc with trivial diff, 3.2 mg%, compared with oil mixture alone ( <i>P</i> =0.17)  % change not provided	on the basis of fatty acid compositionIt is concluded that the unsaponifiable matter of 100 g of corn oil lowers serum cholesterol by something between 6 and 12 mg/100 mL."  Reviewer's Comments: References provided further detail about diets

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
					PUFA) 2) 100 g safflower oil (12% SFA, 10% MUFA, 78% PUFA)  Dietary Intake During Study: Total fat: about 40 g/d  Dietary Intake Assessment/Frequency: Plate rejections recorded  Study Visits/ Measurements: Blood samples collected on 2 d near end of each dietary period		
Tobian and Tuna, 1958	Non- ran- dom- ized trial	С	-	Purpose: To examine efficacy of corn oil in lowering chol in coronary atherosclerosis pts  Actual Sample: 23 pts with CHD  Inclusions: Previous MI HX; current angina pectoris	Run-in Period: None  TX/Duration: Pts instructed to ingest 1- 1.5 ounces corn oil before each meal  Blood samples taken to test serum chol after 12 d on corn oil  Dose/Form: Mazola corn oil	Outcome Measures: TC Phospholipids  Results: % change in TC compared to pre- TX TC: Corn oil diet: -9 to 15%  Change in phospholipids compared to pre-TX level: Corn oil diet: 272 mg/dl to 250 mg/dl	Author's Conclusions: "Actually all the patients, without exception, had decreases in the concentration of cholesterol and phospholipids while eating corn oil"  Reviewer's Comments: Corn oil combined with flavoring agents;

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				Exclusions: None given	Dietary Intake During Study: Total fat (% TE): not reported PUFA (% TE): not reported  SFA (% TE): not reported Chol (mg/d): not reported Calories: not reported  Dietary Intake Assessment/Frequency: None  5 pts instructed to drink corn oil and given no diet restrictions; 18 pts instructed to consume corn oil, avoid butter fat, margarine, hydrogenated veg oil and >1 egg/d; meat allowed 2x/d		use of corn oil as salad oil and cooking oil encouraged
Engelberg, 1957	Non- ran- dom- ized trial	С	-	Purpose: To determine effect of veg oil ordinarily used in salads and cooking processes in group of private pts whose serum lipids and lipoproteins lowered by previous reduction in animal fat intake	Run-in Period: None  TX/Duration: Period of corn oil administration varied from 3-9 mo  Dose/Form: Estimated 15-30 g corn	Outcome Measures: Chol  Results: In 10 subj, previously lowered lipid values not substantially altered following addition of corn oil to diet  Chol and lipoprotein levels incr to	Author's Conclusions: "In the majority (10 of 11) of these individuals the addition of corn oil to the diet for a prolonged period did not elevate serum cholesterol or low-

Author/ Year	De- sign Type	Class	Quality (+,-,Ø)	Purpose/ Population Sample Size	Regimen	Primary Outcome Measures Results	Author's Conclusions/ Reviewer's Comments (Italicized)
				Sample: 12 subj  Inclusions: Private pt; previously on moderately reduced animal fat intake for several y; lowered chol and LDL consistently maintained for ≥1 y prior to addition of oil to diet  Exclusions: Not listed	oil/d - used freely in salads, cooking, baking, frying  Dietary Intake During Study: Milk fat and butter fat eliminated; meat fat reduced; eggs in moderation (6/wk)  Total fat: 40-50 g/d  Dietary Intake Assessment/Frequency: Not provided  Study Visits/ Measurements: Not provided	CNTL values (prereduced animal fat diet) in 1 subj  Subj with xanthomatosis had highly variable lipid values  % change and absolute change not provided	density lipoproteins. It seems reasonable, therefore, to include this highly unsaturated vegetable oil in the diet of those patients in whom it is deemed advantageous to lower blood fats"  Reviewer's Comments: No P values provided

AppendixE2CornOilBloodLipidsType3